

**U.S. DEPARTMENT OF COMMERCE
National Technical Information Service**

PB-265 145

**Hearing on Toxic
Substances Control Act
March 3, 1977, 9:30 A.M.**

Environmental Protection Agency, Chicago, Illinois

3 Mar 77

HEARING ON
TOXIC SUBSTANCES CONTROL ACT

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The Palmer House
State Ballroom
Chicago, Illinois

Susan Panico Dime
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Court Reporter

TECHNICAL REPORT DATA (Please read instructions on the reverse before completing)		
1. REPORT NO.	2. EPA-905/9-77-002	3. RECIPIENT'S ACCESSION NO.
4. TITLE AND SUBTITLE Hearing on Toxic Substances Control Act (9:30 A.M., March 3, 1977)		5. REPORT DATE March 3, 1977
7. AUTHOR(S) Robert L. Duprey, George R. Alexander, Kenneth Johnson, John B. Ritch, Jr. and Karl Bremer.		6. PERFORMING ORGANIZATION CODE
9. PERFORMING ORGANIZATION NAME AND ADDRESS Air & Hazardous Materials Division U.S. Environmental Protection Agency 230 Dearborn Street Chicago, Illinois 60604		8. PERFORMING ORGANIZATION REPORT NO.
12. SPONSORING AGENCY NAME AND ADDRESS U.S. Environmental Protection Agency		10. PROGRAM ELEMENT NO.
		11. CONTRACT/GRANT NO.
		13. TYPE OF REPORT AND PERIOD COVERED
		14. SPONSORING AGENCY CODE
15. SUPPLEMENTARY NOTES Panelists were from Region V and Washington, D.C.		
16. ABSTRACT The introductory part of the meeting dealt with the Toxic Substances Control Act, its purposes, how it is to be put into effect, its benefits, and its potential impact on industry and the environment. The main objectives of the Act were explained in detail, these being: (1) to develop information and (2) to regulate. Panel discussions dealt with pre-market notification and inventory testing procedures; rules of the State programs; and regional toxic substances problems. Questions were then taken from the floor, a number of which were on the subject of exemptions from the Act. Questioners included representatives of chemical companies, engineering firms, State agencies, and other businesses as well as private citizens.		
17. KEY WORDS AND DOCUMENT ANALYSIS		
a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Contaminants Toxicology Wastes	Toxic substances Toxic Substances Control Act	6T
18. DISTRIBUTION STATEMENT	19. SECURITY CLASS (This Report)	21. NO. OF PAGES
	20. SECURITY CLASS (This page)	145
		22. PRICE PCA07/MFA01

PRESENT:

PANEL MEMBERS:

MR. ROBERT L. DUPREY, USEPA REGION V

MR. GEORGE R. ALEXANDER, USEPA REGION V

MR. KENNETH JOHNSON, USEPA WASHINGTON

MR. JOHN B. RITCH, JR., USEPA WASHINGTON

MR. KARL BREMER, USEPA REGION V

MR. DUPREY: It is time that we get started. We're running about ten minutes late right now.

My name is Bob Duprey and I am director of the Air and Hazardous Materials Division, Region V, and I will be the moderator for this session today.

Today I want to introduce the people on our panel up here that will be speaking this morning.

On the far side is Karl Bremer, who recently was appointed the toxic substance coordinator in our region. And we have Ken Johnson from the EPA headquarters, who is the acting Assistant Administrator for toxic substances, George Alexander who is Regional Administrator here in Chicago.

I want to make a couple of announcements, one is we are having proceedings prepared of today's events. As you can see, we have a reporter up here. And when we do go to our question and answer session, we will ask that people identify themselves for purposes of the record on this.

Okay.

Rather than giving further announcements about coffee and lunch for now, I will reserve those for later. But, I think we should get right into the program. So, I take pleasure in introducing my boss, George Alexander, Regional Administrator.

MR. ALEXANDER: Good morning and welcome to Chicago this morning. Luckily, we have rain rather than snow that we thought we were going to have this morning. I suggested to one of my people coming over this morning I prefer to have a little snow, he said he had a lot of sidewalks to sweep and he preferred it to rain. So, I guess everybody has their own preference.

The Toxic Substances Control Act, which is sometimes referred to as Public Law 94-469 represents landmark legislation which may prove to be the most significant in the history of environmental laws. It deals comprehensively with the problem of chemical contamination which has rapidly become a major threat to public health and the environment.

It provides authority not only

for dealing with problems after they had occurred -- our traditional mode of response -- but establishes a whole new approach for identifying and avoiding problems before they occur.

More and more we are coming to understand that environmental protection programs are part and parcel of an effective national health policy that emphasizes prevention. The new Act is a key element of such a policy. It is not perfect legislation, but during the last year we came to realize that if one insisted on perfection, we might never obtain the basic statutory authority that is so critically needed. That we now have strong legislation is a tribute to the good sense of those in industry, labor, environmental groups, and in government, particularly those in Congress who worked together to make this possible.

In February, 1971, a legislative proposal, the Toxic Substances Control Act, was submitted by the President to Congress. Twice during the following five years the Senate and House each passed different versions of the legislation, but were unable to agree on several

key provisions to submit to the President for his signature.

Finally on October the 11th, 1976, former President Ford signed the Bill into law, calling it one of the most important pieces of environmental legislation that has been enacted by the Congress.

The new law which became effective on January 1st, 1977, gives EPA, in cooperation with a number of other federal agencies, a number of additional authorities: to get more and better information about the health and ecological effects, including long term effects at low levels of exposure, the distribution, the uses, the kinds and levels of exposure, of both existing and new chemicals; to help prevent hazards and harm to human health and the environment by taking preventive action against new chemicals before we make major economic investments in them. To balance the various costs, risks and benefits involved in deciding the appropriate regulatory course against a potentially hazardous chemical; to help coordinate the presently fragmentary and piecemeal

federal approach to toxic substances.

Others on the program this morning will discuss the provisions of the law and EPA's implementation activities to date. The main purpose of this meeting is to solicit your comments on our activities throughout in implementing this new and vital law.

I hope there will be an extensive exchange of ideas on the initial regulations for implementing the law, its administration, the economy, its cost and benefits, and its potential impact on industry and the environment. I hope all of you will feel free to let us know of your concerns and your suggestions for implementing this complex legislation.

As I said earlier the new legislation may not contain all of the detailed provisions that some of us might ideally and eventually want. But it is a good foundation upon which we can begin to build an effective program.

However, it is essential to realize that the passage of the law does not

solve the problem of chemical pollution. But it does give us for the first time the authority and opportunity to really begin to deal with the problem.

Let me now describe in a very general way the process by which EPA intends to involve external parties in the administration of the law.

An effort of this sort, as you know, cuts across all the sectors of society. It includes scientists and laymen. It addresses costs and benefits, social and economic as well as health effects, scientific certainties and uncertainties, value judgements as well as matters of fact. It involves a political process, if you will, of a sort that is open, orderly and inclusive, a process that leads without cumbersome delay to decisions and actions that are effective and acceptable because all important views and values have been considered, because all affected and interested parties have taken part, and because the relevant evidence and expertise have been considered and consulted.

It is precisely that kind of process which all of us are engaged in here today. I am convinced it is absolutely essential to the success of any effort to reduce chemical risks while preserving their benefits that we take the trouble, from the very start, to make sure we know what we are doing, to make sure everyone interested and effective is a real part of the process. And we intend to extend that process beyond bare minimum required by the law.

In this regard, the EPA plans to make appointments to recently approved advisory committee, broadly representative of all major interests, to help advise the agency on the implementation of the Act.

The law does not require such a committee, but all along former Administrator Train stated that such a committee should be established whether or not the law required it.

The EPA stated that our first step, following the signing of the Bill into law, would be to enter into an intensive period of consultation with all interested and affected

parties, including industry, health professionals, environmentalists, and other public interest groups, concerning the development of an implementation strategy and the preparation of regulations. This process is well under way and will be discussed in more detail later in the program.

We are determined to administer this new law by the most open and inclusive process possible. We have held preliminary meetings with representatives of industry, environmental and other groups to explore ways of insuring effective public participation in the implementation of this new law. We have met with representatives of other federal agencies to consider how we might work most closely with them. The inner agency committee required by law, which is responsible for developing a list of fifty priority chemicals which deserve testing, held its initial meeting on February 7th of this year .

As one means of insuring adequate public participation, a series of public comment meetings such as this one are being

held throughout the country. The first such meeting was held in Washington on December 14th and 15th, 1976. This meeting is the fifth of nine meetings being held in other cities. And like this meeting today, each is open to all and has been publicized in advance in the Federal Register.

We plan to insure proper public participation in all our rule making throughout the implementation of this Act. We will as a result of this process be able to carry out our responsibilities under the law open and effectively, with maximum public review and involvement.

There are those who feel, of course, that such a process, as embodied in the new legislation and employed by EPA in administering that legislation, that it is far too cumbersome and complicated and that it unduly delays action.

I fully understand this feeling. The public health and well being is today threatened by substances that have been introduced to the environment. We can no longer

accept the time honored notion that every chemical is harmless until someone comes up with a clear cut case that proves otherwise.

However, we also must not accept the notion that every chemical is dangerous until proven otherwise.

I think our only sensible assumption, and it is the assumption that underlies the new law, is that we simply do not know whether a given chemical is dangerous or not, and that before the public is exposed to it, we should go to at least a reasonable amount of trouble to find out.

The protection of public health must always be our overriding concern in administering this law, and we are going to have to make certain that we do, in fact, act as early and effectively as possible to protect the public against unreasonable risk from chemicals. But we cannot, in the real world, decide what those risks are except through the kind of process that I have described.

There can, as you know, be no question of getting rid of all risks from

chemicals or anything else. What we can do, and what the new laws will let us do, is exercise some intelligent and effective control over the risks that we ourselves create. We can bring down to reasonable levels the risks that some chemicals may pose while preserving their benefits.

That, I think, is no small goal, and if we're able to achieve it will be no small achievement.

We have this morning to start off the meeting for you a short fourteen minute film, I believe, on toxic substances.

I am going to ask them to roll that now and then we will move on with the program.

(Whereupon, a movie
was shown.)

MR. DUPREY: It is hard to follow a film like that, I think especially with the presentation I have, which is on the over view of the Toxic Substances Control Act.

I might mention that copies of the Act and summaries were out front. I am sure

you were able to pick them up, which would go into a good deal of more depth than I will be able to do in a short presentation here.

The Act is a very complicated piece of legislation for anyone who has read through it even two or three times. And I am sure the more that can be -- as we go on, we will know more about what it means and how it will be implemented. It is a very complex piece of legislation.

I do have some slides and I will start. Can that be seen okay? Okay. It can now.

Basically the Toxic Substances Control Act was enacted, I believe, because of some of these problems that we have just seen.

As this Herb Block cartoon illustrates, chemicals are all around us, in our air, our water, and our food and in things that one must touch. But these chemicals are essential to our life and their production contributes significantly to our national economy.

There has been a huge surge into the development of synthetic organic chemicals

since World War II. Presently there are an estimated two million recognized chemical compounds.

Chemical sales now exceed one hundred billion dollars per year with over thirty thousand chemical substances in commerce. To these, additional one thousand new ones are introduced each year.

The Toxic Substances Control Act authorizes the Environmental Protection Agency to obtain data from industry on the production, use, health effects and other matters concerning chemical substances and mixtures.

If warranted, EPA may regulate the manufacture, processing, distribution and commerce use and disposal of a chemical substance or mixture.

Pesticides, tobacco, nuclear material, fire arms, and ammunition, foods, food additives, drugs and cosmetics are exempted. These products are currently regulated under other laws.

The administrator of EPA may require the manufacturers or processors of

potentially harmful chemicals to conduct tests on the chemicals. Testing may be directed to evaluating the characteristics of a chemical, such as persistence, or acute toxicity or to clarify its health and environmental effects including carcinogenic, mutagenic, behavioral, and synergistic effects.

Before required testing the administrator must set forth the need for such tests.

Basically in doing this the administrator must find that the chemical may present an unreasonable risk to health or the environment or there may be substantial human and environmental exposure to chemicals. Number two, their insufficient data and experience for determining or predicting the health and environmental effects of the chemical, or testing of the chemical is necessary to develop such data.

The law authorizes the formation of an interagency committee at the federal level to advise the administrator of EPA of which chemicals should be tested. The committee may

designate at any onetime up to a maximum of fifty chemicals from its list of recommended substances for testing.

Within one year of the Act the administrator must either initiate testing requirements for those designated chemicals or publish in the Federal Register his reason for not initiating such requirements. That is for existing chemicals already in the market.

For new chemicals, the law provides for pre-market notification. A manufacturer of a new chemical substance must give the administrator ninety days notice before the manufacture of the chemicals.

Any chemical which is not listed on an inventory of existing chemicals to be published by the administrator by November, '77, will be considered new for purposes of the pre-market notice requirements.

Also the administrator may designate a use of an existing chemical as a significant new use, based on consideration of the anticipated extent and type of exposure to human beings or the environment.

For these new chemicals, the administrator may determine that there is inadequate information to evaluate the health or environmental effects of a new chemical, whether or not it is on the list I have described before. In that event, he may issue an order, forty five days before the expiration of the pre-market review period, to prohibit or limit the manufacture, processing, distribution or commerce use or disposal of that chemical.

If the administrator finds that there is a reasonable basis on the basis of the information submitted that the new chemical would present a risk to either health or the environment, he may follow a similar procedure involving an order to prohibit the manufacture of the chemical.

Exempt from pre-market notification requirements are chemicals included in the category of chemical substances listed on the inventory of existing chemicals, produced in small quantity, solely for experimental or research and development purposes, used for test marketing purposes, and for determining

by the administrator not to present an unreasonable risk.

The Toxic Substance Act in Section 6, provides for regulation of the hazardous chemical substances and mixtures.

This authority is limited to those which are on the list of fifty existing chemicals.

The administrator may prohibit or limit manufacturing, processing, or distribution in commerce use, or disposal of the chemical substance.

The labeling may be required for a chemical or any article containing a chemical. The manufacturer may be required to make and keep records of the processes used in manufacturing the chemical and conduct tests to assure compliance with any regulatory requirement. Further, the administrator may require a manufacturer to give notice of any unreasonable risk of injury presented by its chemical to those who purchase or may be exposed to that substance.

A manufacturer may also be required

to replace or repurchase a substance which presents an unreasonable risk.

I might mention that under this same section of the Act, the Congress specifically directed the administrator to take action with respect to PCB's, Polychlorinated Biphenyls, by issuing labeling and disposal regulations by July of 1977.

In addition, the Congress specifically prohibited the manufacture of PCB's after July of 1979.

I did want to mention briefly one other section before reporting, that is Section 7, which provides for imminent hazard authority; that is, if the administrator finds the chemical presents an imminent and unreasonable injury to health or the environment, he is authorized to go to court to seek an injunction to obtain appropriate relief.

With respect to record keeping and reporting, the law authorizes the administrator to issue rules requiring manufacturers and processors to report to EPA the name of each chemical, its identity, its proposed

uses, estimates of production levels, descriptions of by-products, adverse health or environmental data, number of workers exposed to a chemical.

The manufacturers of chemical mixtures and research chemicals are exempt from these requirements unless the administrator determines such warning is necessary to enforce the Act.

Similarly, in absence that -- of a determination of reporting is necessary, because of unreasonable risk small manufacturers are exempt from reporting except for chemicals that are subject to proposed or promulgated testing requirements and limitations under the regulatory provisions of the Act.

The administrator is specifically required to list all existing chemicals by November of 1977. This list will be continually updated after that date.

The law requires any persons making a chemical substance to keep records on significant adverse reactions to health that are allegedly caused. Records concerning

employees must be kept for thirty years,
other records for five years.

In addition, the administrator
may request that specific health and safety
studies be conducted on certain chemicals.

The Act is quite clear in terms
of its relationship to other federal laws, inas-
much as the Toxic Substance Control Act cuts
across all environmental legislation and even
other legislation.

The administrator may determine
that the risks presented by a chemical may be
sufficiently reduced by action under federal
law not administered by EPA. If he does, the
administrator requests the agency administering
the other law to determine whether the risk
exists and if the agency's action would sufficient-
ly reduce the risk.

If the agency finds no risk or
takes actions directed to this, EPA may not
take any regulatory action directed to the same
risk.

In addition, the law directs the
EPA administrator to use other laws administered

by EPA to protect against unreasonable risk, such as the Federal Water Pollution Control Act or the Clean Air Act, unless the administrator determines that it is in the public interest to protect against such risk using the Toxic Substance Control Act.

With certain exceptions as set forth the Act does not effect the authority of a state or political subdivision to establish regulations effecting chemicals. However, if EPA issues a testing requirement for a chemical a state may not establish a similar one.

If EPA restricts the manufacture or otherwise regulates a chemical under the Act, a state may only issue requirements which are identical mandated by other federal laws, or they may prohibit all together the use of the chemicals.

In response to request by a state, the administrator may grant an acceptance to this provision under certain conditions. Specifically, the administrator must find that the state requirement would not cause the person or activity to be in violation of the Act, and

too, would provide a greater duty of protection and not unduly burden interstate commerce.

This is the end of the slides. Some other sections of the Act that are briefly explained beyond the state provisions are in the enforcement area.

The Act does authorize for violations of civil penalty of up to twenty five thousand dollars per day for each violation and criminal penalties of the same amount.

It provides for authority for the administrator or his representatives, his inspectors, to inspect establishments in which chemicals being regulated are distributed in commerce. It is subpoena authority and information gathering authority as well.

Judicial review proceedings are provided in those instances where someone effected contests the regulation as issued.

There are also provisions that deal with research and development of data systems and technical assistance. Some of these things we will get into further today, but it has been established in the Office of Toxic

Substances and Special Technical Assistance Office, under John ~~Ritch~~ who is here somewhere today and will be of course into that more.

Basically, that is a quick overview, although I am running longer than I should. And now I think I'll turn it over to Ken Johnson.

Ken Johnson is holding two positions, currently he is Deputy Regional Administrator in our Austin Office and it was thought by headquarters apparently that he was the best person in the agency to get the Toxic Substance Program off the ground, and was appointed acting Assistant Administrator for Toxic Substances for an interim period, I assume until a permanent Assistant Administrator is named. So, I take pleasure in introducing Ken Johnson who will speak on implementation activities that will be going on on this Act.

MR. JOHNSON: Thank you, Bob.

I think rather than being the best person available, I was the most available person for the job.

I am happy to be here because

I was born and raised no more than fifty miles from Chicago. I really consider it to be a home for myself, so I am always glad to come back here.

I am going to talk about what we're doing now to implement the Toxic Substances Control Act in specific terms. And I want to begin really by reading verbatim three policy statements at the beginning of the Act, very short statement, which really provide the thrust and the substance of the Act itself. After I read each of them, I am going to interpret them as I and the agency are interpreting them right now.

The first policy statement says, "Adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."

And that puts the burden, of course, upon the manufacturer and the processor,

not so much that evidence can be provided for a regulatory action by EPA to cut off production or otherwise limit the distribution or use or disposal of a material. Although, that may be necessary. Not so much for that, but really to build into the whole process of developing chemical substances for commerce, to build into that whole process the earliest possible recognition of the potential impacts -- adverse impacts upon human beings and other forms of life. The earliest possible sense so that corrective actions can be taken at the least expense to the manufacturer and processor and at the least expense to human beings and the environment in general.

It's really the same philosophy, I think, that's required into the National Environmental Policy Act for federal agencies. Every time we plan a major federal action we are to take into account the expected environmental impact and make corrective actions. And I think it is that philosophy, rather than the regulatory philosophy, which lies at the heart of the Act and which will protect not only

this generation but future generations.

But there is no doubt that the burden is upon the manufacturer to develop information on expected adverse impacts.

The next policy statement says that, "Adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable and " -- I underline that consciously -- "An unreasonable risk of injury to health or the environment and to take action with respect to chemical substances and mixtures which are imminent hazards."

And there the burden really is upon the agency. As we go on in the administration of this Act to really define unreasonable. And unreasonable really means that we weigh in the balance, the expected impact or the actual impact of human beings and other forms of life, against the cost of eliminating those adverse impacts. And the burden there rests in a great degree upon the agency itself administering the law.

But it is clear in that policy statement that if regulation isn't necessary,

control is necessary in a formal sense and it be carried out.

The final policy statement, a lot of people, especially those people who are going to be regulated by this Act may feel it is sort of a motherhood statement, if that is the right word to use in this particular case now.

It says, "Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovations and commerce and such chemical substances and mixtures do not present unreasonable risk of injury to health and the environment."

Again, the burden is upon the agency to carry out the administration of the Act in a sound and effective manner, but in a fair manner, in a manner which does not impede unduly technological innovations and commerce.

I said that these three policy statements really are the thrust and substance

of the Act, and that is true. Every section coming on really just expands upon those policy statements. And I will talk now about -- about what we're doing to implement the law.

And I am going to begin by talking really about why we are all here today, and that is, public participation. As Bonnie Bray had said, "We mean to involve as many people as possible in going ahead to implement this law." And as this slide shows, we have both long-term and interim steps which we're taking.

Long-term steps have been eluded to already. We are in the midst of forming a policy advisory committee to the agency to consist of wide representation as possible. And we have asked within recent weeks for nominations for this committee. And we have asked that in an announcement in the Federal Register. And anybody that is here that would like to send nominations over to us, can address them to me in Washington, or address it here to the Regional Office to Karl Bremer who will see that we get them.

We need within the next month or so to establish this committee. It is going to consist of sixteen members from as wide a spectrum as possible, from official environmental groups, from academic interests, from labor unions, from industry, from as many walks of life that have a specific interest in this particular law.

The next thing we're doing, and have done already, is to establish -- although it is in very small form now -- an industry assistant's office, that can serve really as a point of contact by industry, those people who are going to be regulated for information on the law, on specific regulations, on how we are carrying out our responsibilities under the law.

And John Ritch, who is flying in this morning from Washington, should be here this afternoon, is in charge of this office. And when I came here this morning I brought several hundred copies of an announcement giving an address for John Ritch in Washington and a card which you could send back to be put

on our mailing list for information as we send it out.

If you didn't get a copy of that, I can -- I can give you -- spell his name for you right now, John Ritch, R-i-t-c-h, and you can -- even though this may not be the exact wording on the information that is really the same address. You can address it to Room 207, Environmental Protection Agency, 401 M Street, Southwest, Washington, D.C.

He has a new telephone number, I am not sure what it is, you can pick that up this afternoon if you want to call him.

We also in the long term are going to go out of our way in the development of each regulation and rule under this law. And we can really do nothing less except by formal rule and regulations. We are going to involve public participation in the development of the regulations, and we have done that today. And I will describe that as I go a little further along and define what we are going to do. Each and every regulation is going to be developed in the open and full par-

icipation and public meetings.

And interim steps, we have -- already have had public meetings such as this in other cities across the country. We had a large public meeting in Washington on December 14th and 15th to solicit comments by everybody concerned on how EPA should develop its basic strategy for carrying out the law. We have moved ahead now and have produced an interim strategy document, not a completely final one, and we're right in the process now of mailing that out to everybody in the center. We are sending one hundred copies to each Regional Office and we will follow that up if necessary. We invite environment groups, and industrial groups to pick up a copy. We are sending out copies to the mailing lists that we have of the strategy documents. We need to have on Washington March 22nd and 23rd another large public meeting in the Jefferson Auditorium of the Department of Agricultural Building on Independence Avenue on the mall in Washington to receive comments on the strategy documents, and also to receive comments on what the final strategy docu-

ment should be. That is on March 22nd and 23rd, and each of those days the meeting will begin at nine a.m.

We also have had already public meetings on two rules which we're developing under section six of the Act. One rule has to do with the labeling and disposal rules for polychlorinated biphenyls, the chief subject -- one of the chief subjects of the movie you saw. That is in response to having -- I think it is section sixty of the Act. We have had public meetings on that.

We also had public meetings on the rule which is being developed for non-essential aerosol use -- uses of chlorofuran carbons. We need to have meetings after the opposed rules come out in the Federal Register as well.

And finally, really an anticipation of our policy advisory committee which I have described, we had meetings with representatives of some nineteen organizations, both environmental and industrial organizations, to get council and advice as we began implementing the law. We have had two or three meetings

with that group. But that group -- that informal group will be dissolved when we have our formal policy advisory committee.

This slide just indicates the time schedule we're at now. We're in March of 1977, having public meetings of the strategy documents.

We mean to have this document and this strategy but not -- not one which has produced one and then guides us forever. We have to recognize now that we're starting with a relatively limited basis of information, and as our information gets better and we get smarter, we're going to approve and expand upon this strategy to guide us into the future. We have task groups and work groups working on this right now. That is on the basic strategy for carrying out the law.

The second strategy which is being developed, which is to integrate all of the actions of the agency under this law and other laws so that we have a common or at least consistent direction.

As pointed out by Bob Duprey,

section six of the Act requires the agency to consider whether or not another piece of federal legislation, such as the Clean Air Act or the Federal Water Pollution Control Act of 1972 might not be a better vehicle for controlling certain toxic substances. For example, it might be best if a toxic substance appears only in the discharge into the water from an industrial plant to apply a rule under the National Pollutant and Discharge Aluminamation System, under the Federal Water Pollution Control Act, rather than the Toxic Substance Control Act. We have to have people working together. We have had people in our office, research and development working hand and glove to develop test protocols for toxic substances. We have to have an integrated effort on the part of our office of enforcement so that it works smoothly. And I think that second strategy is also being developed with approximately the same time frame that is shown here.

I don't want to frighten you here or make you think that EPA is just a big bureaucracy, but I want to discuss a little

bit more here the basic rule making process that we go through. And I think it is probably similar in other -- in other agencies as well.

In the development of a rule or regulation a lead office is designated to do the basic work, basic staff work. And that under the Toxic Substances Control Act would be basically the Office of Toxic Substances.

They would develop a development plan -- a concise development plan for any rule, showing its needs, and how they propose to go ahead under what schedule. That development plan is then sent to the administrator who approves it. And a work group is formed. A work groups consists of not only people from the Office of Toxic Substances, but also other offices within the EPA that have a legitimate role to play, such as the Office of Enforcement and the Office of General Counsel, and also the Office of Research and Development.

In addition, the work group includes people from other agencies that have special expertise or knowledge that can play

a part. And we also go outside the agency where necessary to get talent. That group prepares a proposed rule, which is eventually reviewed by a steering committee, consisting of representation from each of the Assistant Administrators in the agency. The administrator approves that, it is published in the Federal Register for comment. During that period -- prior to that, as I said before, we do have public participation in public meetings in preparation of the rule, published in the Federal Register for public comment for a certain period of time, depending on the rule. And then based upon comments made, provisions are made to the proposer and final rules are made. And they come to us through the steering committee. It is approved by the administrator and it is then finally published in the Federal Register.

It is a process which seems complicated, but it provides for attention by all interested parties within the agency and without. It does not have to be extraordinarily time consuming. But it does provide an opportunity

for, as I said, the interested parties to take part.

Now, I will talk about some of the rules which are under development right now.

As it was pointed out by Bob Duprey, under section four of the law, the agency if it has a reason to believe that a certain chemical substance has a potential or actually is causing harm to human beings, but does not have sufficient information at hand to clearly define that, a rule can be developed -- must be developed under section four by the agency requiring the manufacturer or processor to develop information which is necessary. A development group has been formed. The output of this development group in terms of basic policy framework for general testing requirements will be produced in July of this year.

We expect the basic forms and procedures which will be covered in a general sense to be proposed in September and made final in December.

During the process, we're going

to take a test chemical substance or classification to indicate what we have in mind for -- for the rules for testing that we would be asking. That would be proposed in December of this year with final rules in March.

We want to make it clear that we're going to be as specific as possible in asking for testing. We're not going out on any fishing expeditions, but really in priority fashion, defining those chemical substances that we're especially concerned about first and working toward those.

Now helping us with that, and in fact providing perhaps the greatest influence upon the agency in asking for testing rules will be the interagency committee which section four A of the Act establishes, consisting of recommendation from the Environmental Protection Agency, the National Cancer Institute, National Institute of Occupational Safety and Health, the Commerce Department, the National Institute of Environmental Sciences, the Council on Environmental Quality, the National Science Foundation. I don't know if I've named

all, but you can get an idea of the type of people that are involved.

By September 30th of this year this committee is supposed to come up with a list -- a priority list of fifty chemical substances, and the agency has to respond to that list. The list is the priority list for testing rules to be developed.

I want to make it clear now that it is likely that the interagency committee may specify classifications of chemicals as well as individual chemical substances. Because if -- if a given classification of chemicals has been shown to have a significant number of say carcinogenic, or mutagenic, or teratogenic chemical substances, based on past research, then the entire classification subject. And it is entirely likely that the interagency committee may specify a classification of chemicals for testing, which, of course, expands the number of individual chemical substances will be involved.

Even though we have a year to respond to the interagency committee and say,

"No, we don't want to test those" if we so choose, I doubt very seriously with an organization like the interagency committee would very likely refuse to promulgate rules for anything that is on the list that the interagency committee will specify.

They can specify fifty chemical substances not entirely certain that they're going to specify all of those fifty the first time around.

The committee has met several times. A man named Dr. Warren Murer (phonetic) has been chosen as interim chairman of this committee. The committee is meeting on a weekly basis with an all day long meeting open to the public. And it is likely that it will move ahead very expeditiously.

I think as they go along, they will probably define the criteria that is going to be used in establishing the priority list for chemical substances. Some time this summer there is likely to be an interim report, though I can't guarantee that.

This slide is missed named,

because it shouldn't say pre-market notification. Section five talks about pre-manufacturing notification, and that's what should be recognized by everybody who might be regulated under it. The agency is responsible, as I will talk in a few minutes about, for establishing the initial inventory of chemical substances in commerce or which have been in commerce within the last three years. And that list inventory of chemical substances is to be published on November 11th of this year -- November 11th, 1977; that is three hundred and fifteen days after the effective date of the Act which was January 1st of this year. Thirty days after that any new chemical substance which is not on that inventory, or any significant new use of a chemical substance. For example, a greatly expanded production of the chemical might be considered a new use. If there are chemical substances, new ones or significant new uses, the manufacturer or the processor has to come to the agency with a pre-manufacturing notification.

We are working on developing

the basic requirements for that pre-manufacturing notification which will come due on December 10th of 1977. We expect to have a proposal in July for that with the final rule in November.

We also will have a task force working within the agency to determine how we are going to review pre-manufacturing notifications. And we'll make this our review guidance to ourself known publicly, so that a manufacturer or processor will know in advance how the agency is going to address the information sent in by the manufacturer.

The manufacturer essentially will send us in a notification demonstrating that chemical substance will not cause an unreasonable risk to human health or the environment.

I want to talk now just briefly about some of the section six regulations or the basic enforcement regulations which were developing now.

As it is shown on this slide, the law requires that the agency specifically develop regulations on polychlorinated biphenyls.

And the first one that comes up is that we are to by July 1st of this year, establish the rules -- promulgate rules covering labeling and disposing of polychlorinated biphenyls. And there is a subsequent rule which will apply to closed manufacturing -- closed circuit manufacturing and the total manufacturing on into the future.

I can tell you now two of the issues which have come upon polychlorinated biphenyls, which will indicate not only for this chemical substance that we're developing a rule for, but for others into the future, the kinds of difficult decisions -- difficult issues which the agency will confront, which the public really will confront. Take the disposal regulations for PCB's. Because this chemical substance is very long lived, has been shown to be toxic, the agency is confronted with both the philosophical and engineering issues. If we are under this law not only to protect this generation but future generations, we have to determine the best means of disposal to protect those future generations. And you

might think about that as the really only way to move ahead is to require destruction of the PCBs. And destruction in this case means incineration, you will wipe it out and there won't be any worry.

The thing is when you do it that way, you're involving a process which may not be perfectly operated and maintained. And there may likely be PCBs entering the atmosphere due to inefficient or incomplete combustion. So, if you require destruction in the rule, you would have to also build in a certainty that you would have a well designed, well operated and well maintained incineration facility and that would have to be built-in. You might choose on the other hand to say on the other hand if we are going to introduce PCBs into the environment by the process of destruction why not consider long term storage as a solution, build a chemically secure landfill and place it there, and you don't have to worry about incineration. But if you did that, then you'd have to be somewhat concerned about whether that chemically secured landfill would be a

chemically secured landfill on into the future. Would the land be only dedicated for that purpose, would you have adequate supervision of that landfill.

The issues are very difficult. We are addressing them, and we intend to have a proposed rule for both labeling and disposal of PCBs on or about the first of April this year.

We also are developing rules for non-essential aerosol use of chlorofuran carbons. We intend to have a proposed rule available for that during the last week in April. I think the 26th of April is our target date. That coincides with the date of an international meeting which EPA will host in which we will discuss common regulations or at least consistent regulations for eliminating non-essential aerosol uses of chlorofuran carbons. and other fluorocarbons from around the world, so that we not only protect the ozone layer over the United States, but everywhere all over the world.

The last items on there is attorney's

fees, which is a federal rule in section six, which allows the administrator to pay reasonable attorney fees associated with some of the rule development, some special fees for expert witnesses and all that.

The Act, of course, has its two policy features, of course, one to develop information and one to regulate, the basic ones. We are developing more groups and rule development on the reporting required. And I want to emphasize here that we are not going to go out on fishing expeditions, we're going to be as specific as we possibly can in the development of information. For example, many initial rules under the general reporting required under section eight A of the law -- we are shooting for a target date of August of this year -- that provision of the law allows us to ask for production data and the like, use data. The kind of information that will allow us really to take toxilogical information on specific chemical substances and try to as best we can develop information on the population at risk, human beings and other

forms of life, so we can determine where the regulation is needed; determine the kind of regulation that is needed on a specific basis as possible.

The next item here is the initial inventory. I mentioned that by November 11th of this year the agency would publish a list of all chemical substances in commerce or which have been in commerce in the last three years under section eight B of the law.

The acting administrator, John Corals, (phonetic), signed the proposed rule applicable to this. We are sending it to the Federal Register today, I expect it to be published in the Federal Register sometime next week, I can't give you an exact date, it will be sometime next week, the rule that applied to the initial inventory.

It is likely that within the next thirty days or so -- in fact, it is not only likely, it is going to happen, we're going to publish a candidate list of the chemical substances we believe to be in commerce

or which have been in commerce. That list will include some thirty three thousand chemical substances. The list will include the common names of those, so I think there is as many as one hundred and fifty five thousand common names included in the list. We will publish it alphabetically, according to the name of the chemical, we will publish it by the chemical aspect system service number, we'll publish it in alphabetical order according to the formulation.

If there are chemicals which can be identified only by structure, the manufacturer is to go to the chemical abstract service and get a special number for it. On the reporting forms which will be quite concise, report that information to the agency.

We're asking that the manufacturer confirm that he is manufacturing a chemical substance which is on the list, or if the chemical substance which he manufactures is not on the list to report to us on a form which will be included in the proposed rules, so that we can make this list as complete as

possible, because it is in the interest not only of the agency to develop a knowledge of the chemical substances which are in commerce, but really to make it possible for all substances to be included in the initial inventory, so we don't place an undue burden on individuals and processors. We expect the final rule and the final list to be published in November of this year.

We are working on basic record-keeping as well and we will complete that during the fall of this year under section eight.

The health and safety studies which are listed here have to do with section eight C, D, and E of the law.

Section eight C says that information pertaining to health impacts upon employees must be maintained by the manufacturer or processor for thirty years. Information on health impact upon human beings other than employees must be maintained for five years. Section eight D says that manufacturers and processors are to send to us

lists of health and safety studies they have for the chemical substances they produce, and to send us the actual studies themselves.

All these will -- eight C and eight D will be -- requirements for that in the actual recordkeeping and reporting will follow specific rules to be set up. And we are not asking you to embark upon recordkeeping right now to satisfy us. Although, it is to your advantage, I believe, to keep records of adverse impact information on health and safety studies for your own information and for that of the people who are your employees and industry or the people to whom you sell the material, the people who use it.

But, we will ask for specific information, and that will be developed by rule and you will have a chance to participate in the development of that rule.

Section eight E says that on the effective date of the Act, if a manufacturer or processor obtains information showing a substantial impact upon human health or the environment that information is to be sent to

the Environmental Protection Agency.

Substantial impact or substantial risk, the words that are in that section of law are not defined by the law. We intend to establish a development group for those three sections, C, D, and E, momentarily. One of the first things to be done, is to prepare and publish guidance on section eight E; what do we mean by substantial risk; what kind of information are we expecting; who is responsible for sending in the like, I would expect in the next thirty to forty five days that will be published in the Federal Register as guidance.

The last item that we have here on definition of small business, that is there because section eight A of the Act, which is the general recordkeeping provision, exempts small business. We have not defined small business yet, we will be doing that over this summer -- certainly before the recordkeeping roles are promulgated.

We welcome, we solicit any opinions by anybody as to what a small business should be. We will be working with the Small

Business Administration on that definition.

I guess most people in industry would say that a small business is their own business and smaller, I guess. You can't have everything.

The date on that slide, could be initial date for initial request on health and safety studies be 6-77 -- or 6-78?

MR. JOHNSON: It will be --

A VOICE: Is it going to proceed the proposed rule of 9-77?

MR. JOHNSON: No, you are right, it's going to be 6-78.

A VOICE: 6-78?

MR. JOHNSON: Right.

The record, of course, which are going to be kept will require that the agency have the best possible system for information storage and use, because there is a lot of work here. And it is our intention to the greatest degree possible to simplify the recordkeeping provisions, the information provisions, to the greatest degree possible to be consistent with the primary purpose of the

Act.

We do have people in health and from outside the agency working together to develop a good information system, a concise one, that uses information in the most efficient fashion. We are also working with other federal agencies, such as HEW, and the Department of Labor to pull together a common and consistent system. That is a requirement of section ten of the Act, that we work together and produce a system which is not redundant. We are going to try to provide the greatest -- try to avoid redundancy.

The other activities under the law that have been touched briefly upon by Bob Duprey, we will have state programs. There is a small amount of grant money available in each of the first three years of the effectiveness of the Act, about one million and a half dollars.

Some states -- a few states believe that we should have a relative handful of demonstration projects which will show what a state can truly do and serve as a model for

other states. Some other people feel that we should take the million and a half each year and divide it among the fifty states which is a very small amount of money going to each state to begin establishing a program in each state.

We will be determining over the next few months the way the agency is going to go. And we are going to be involved directly with the Regional Office and the state in making that -- in making that decision.

We're also working, of course, to make sure that sections of the law that deal with exports and imports are properly handled.

Importers, of course, are considered as manufacturers. On exports, we have to notify the country receiving the export about the chemical substance. And whether we have any rules on testing or regulatory rules on the export of materials, and to supply them any health and safety studies which are involved.

We're all going to be working on all of the other things which are listed here on the kinds of inspections that we will

be making under the rules and enforcement procedures under the rules, under section six and section seven.

The employee protection provision here protects employees against any adverse action by their employer if they take part in a rule making or provide information to the agency about a health impact or ask for any testing on a program to be carried out.

We will have on all of the things I have listed here, financial disclosure, hearing procedures, and especially confidentiality and a very specific rules development. And the Act makes it quite clear on confidentiality that we are to protect confidential information if it is asked of us during reporting, during all the provision of the Act. Except, we cannot keep health and safety study information on specific chemical substances confidential. That we cannot do.

That is the last of the slides.

That is a brief overview of what we are doing right now.

During the question and answer

section, I will be happy to answer any questions that you can raise, to receive your comments and take your comments into consideration, as we move ahead with the information of the Act itself.

Thank you.

MR. DUPREY: Okay. Thank you very much.

At this time, we are ready for a break. I would ask -- we have had some request from people on smoking. This is a crowded room today. I think maybe the best way to handle it is when we come back from break if we can separate the room, have the -- I guess, the non-smokers let's say on the right side -- my right side and the smokers on the left side. I think it would help quite a bit.

I think in order to provide as much time as possible for the question period that we should try to keep the break to around ten minutes.

You do have cards that were handed out in terms of writing down the questions that you have that we will receive after the break. We will have someone come down the aisles

and pick them up. I would ask that you put your name on the card so that I can identify for the proceedings.

Thank you.

(Whereupon, a short recess was had).

MR. DUPREY: I think it is time to get started again.

The procedure we have selected to use to handle this question and answer period, and also this is the time where we hope people who have some remarks they want to make separate from the question sort of thing, we can use for that.

I might remind you we do have specific panel sessions on three different areas this afternoon where we can get into a good deal more depth on some matters. We have a panel session on the rules of the state programs, which is very important to us here in the Regional Office. We have a section on the pre-market notification and the inventory testing procedures, which is, of course, the heart of this law. And we have a section which

later -- which is on the regional toxic substances problems and there will be considerable discussion on that I am sure.

The procedure we have selected to have -- use these cards. And if people have questions written down on these cards we'll pass them to the aisles, we will have someone come down and pick up these cards. I don't see anybody in the back that can pick them up right now.

We will then go through some of these questions that are written on the cards. We hopefully will avoid some duplication. And, however, I will make sure that we leave some time so that people who want to make some direct remarks -- we have a microphone that is part way down here for that purpose. Here come our people to pick up the cards.

The first question I have is from Jake Parikh, P-a-r-i-k-h, from Upjohn Company, Kalamazoo, Michigan. "Chemicals used exclusively in pesticides, foods, drugs, and cosmetics are exempted from TSCA. Are chemical intermediates, in a multi-step synthesis leading

to a drug exempt from the Act?" And I will ask Ken Johnson to speak to that.

MR. JOHNSON: That is an area which has not been fully covered now. I would think as we go ahead into the future, if we have toxicological information which would indicate that some of the raw materials or some of the intermediate products in the production of a drug, or of a pesticide has a potential for -- for harm, or could cause harm, then I think under the Toxic Substances Control Act specifically for that chemical substance we could require record-keeping of the industry involved, we could take action under the Toxic Substances Control Act for that material.

I discussed that just last night with a representative from our office of general counsel. That is still being discussed in the agency.

But, I think our point of view there is that if the Federal Insecticide, Fungicide and Rodenticide Act, or the Food, Drug, and Cosmetics Act leaves a gap and does not adequately cover a material which is of harm

or potential harm to human beings or other forms of life, then we would seek to use the Toxic Substances Control Act. But, it would be in a very carefully chosen manner. But, we would not leave the gap if we possibly could.

I want to make it perfectly clear as I pointed it out, pesticides themselves as pesticides, and drugs as drugs, are not covered by the Toxic Substances Control Act. The intent of the Congress in drafting the Toxic Substances Control Act was to mesh with the other Acts and to cover areas that were not covered.

MR. DUPREY: As part of this question, Ken, also, "Are the chemical intermediates leading to products of commerce required to be on this inventory list?" And also, "Are the known side reactions products, occurring in small quantities in the manufacture of chemicals for commerce required to be on the inventory list?"

MR. JOHNSON: That question is very specifically addressed in the proposed rule

for the initial inventory. What it says basically is that intermediate products that lead toward the final product are to be reported in the initial inventory.

By-products, those that don't lead to the end product are included, at least in the proposed rule.

Some people believe within the agency, and I am sure some people believe outside too and will comment during that comment period, that these by-products in and of themselves have such substantive quantities or such toxicities that we really should have information on them. We can, of course, ask for by-product information, and undoubtedly will under the general recordkeeping provisions of section A.

Some people say that because the small manufacturers are exempt from the general recordkeeping requirements, we don't have to ask for by-product information now, we will have a difficult time doing it later on with the small manufacturer. That obviously is going to be discussed during the public

comment period on the proposal.

MR. ALEXANDER: Ken, we have a question that relates back to the pesticide question again, that I think is a very good one. The question is; "Where you have something that is a pesticide and is regulated thereunder, but where it also has a very significant use as a non-pesticide, what is going to be the position of TSCA on that?" An example of that would be Mirex.

MR. JOHNSON: It is our intent that if in the other use, say as an industrial chemical or whatever, there is an unreasonable risk to human health or the environment, and if that use is not controlled by the Federal Insecticide, Fungicide, and Rodenticide Act, that then we would attempt to control that under the Toxic Substances Control Act. That applies to a lot of chemicals.

I have asked specifically for a legal opinion from our Office of General Counsel on that very matter, and I expect to get it momentarily. We will make that opinion by the General Counsel public.

MR. DUPREY: Okay.

I think we're going to continue on the questions that deal with these exemptions. We have a number of them. This is from Ken Karasavage, K-a-r-a-s-a-v-a-g-e, Meade -- Johnson. "Please go into more detail on exemptions for the food and drug industry. One: how about chemical intermediates generated in the production of a final drug substance. Two: how does the law apply to chemicals which are used both in the food and drug industries and other industries?"

That has probably been answered.

MR. JOHNSON: I think the first one was too.

MR. DUPREY: Okay.

From Mr. Goodman, G-o-o-d-m-a-n. "What interpretation will be given to the exemption in section three two A of "Any pesticide" for a substance like Mirex that has been used as a pesticide but has had even a larger volume of use as a flame retardant or other non-pesticide substance than it has had as a pesticide?"

I believe that has been answered.

MR. JOHNSON: I believe it has been answered.

MR. DUPREY: We have a number on the same thing. James Nickerson, Abbott Laboratories, "If drugs are exempt, should intermediate chemicals manufactured to make the drug be on the inventory list? And does it make a difference if the intermediate is shipped from plant to plant, or state to state?"

It sounds a little different.

MR. ANDERSON: Yes, that is a little different.

As I understand it now, those intermediate would not be on the -- on the inventory list.

However, as I pointed out before, if we obtain information which shows a specific chemical has a potential for harm then we will ask for general recordkeeping under section eight A of the law, and under section six or section seven.

As I understand it now the inventory would not include those substances.

MR. DUPREY: This question is from S.M.

Darling, D-a-r-l-i-n-g. "There has been considerable discussion of test protocols for health effects, such as carcinogenicity, but little about ecological effects such as persistence. What sort of test protocols are foreseen for environmental and disposal effects?"

And I will read the second part of the question, "Mention was made of the exemption from pre-market notification for chemical substances which the administrator considered to be safe. How will the manufacturers know that the administrator considered a new substance to be safe? Can new substances be considered exempt if it is not on the administrator's list of risk chemicals, or categories of chemicals? Or is application for an exemption under section five H4 can't amount to pre-manufacturing notification?"

MR. JOHNSON: There is no doubt as we begin implementation of this Act that we are beginning with limited information. We will have little or no information with regard to impact upon human health at the beginning, and even less upon impact upon other forms of

life.

As we move forward in the development of rules for testing, if the inter-agency committee finds chemicals to be tested, they will be discussing really the types of tests which are to be involved, the sequence of tests which are to be applied, we will ask our office of research and development to develop new test protocols for other forms of life besides human beings, and also for human beings.

As we go on in the future we will just get better and better and better. But, right now, admittedly, especially with regard to other forms of life in the environment we are going to be starting with a very limited data base.

I would think with regard to looking at new chemicals coming in somewhat of the same would apply. Without a doubt we're going to in priority order concentrate upon those chemical classifications for which we already have information to show some harm, and really concentrate on those.

We will undoubtedly have some form of series of tests which would narrow down upon those which we would consider to be of priority nature. And have lesser investigations of those for which we have no evidence at hand to believe they're anything but innocuous.

Now, that is not the perfect system obviously, because it really is as good as our data of information is at any point of time. It is only going to be through additional research, additional development of test methods, and determinations of chemical substances that we're going to be smarter and smarter about chemical substances.

It is also true that we are going to have to operate within the personal resources we have at hand. It is not going to be a perfect system in the beginning. We are going to use our best judgment based on the best information we have at hand to do the best job right away.

I would guess that there will probably be chemical substances which will

go through our screen later on and be shown to cause some harm, based upon our present ignorance. We are going to try to reduce that information gap as quickly as possible. We are going to do our level best to protect human beings but it is not going to be perfect at the beginning.

MR. DUPREY: Okay, thank you.

This next question is from R.K. Null, N-u-l-l, Chrysler Corporation. "Normally what will be the time period between publication of a proposed rule and public hearing on comment date? Will it be possible to petition for a delay if we feel that the time period does not allow time to review thoroughly and prepare comments?"

MR. JOHNSON: Well, let's see, on the proposed rule for PCBs, we're going to propose it about the first of April and then promulgate it on the first of July, so that's a three month period. That is an approximate time period we feel for overall.

You can certainly petition for time. And if a comment is made to us that we

are not allowing enough time we will allow more, but a convincing case will have to be made by the petitioner.

And there will be public meetings and public hearings during the commentary.

MR. DUPREY: This next question is from Snvesh B. Damle, D-a-m-l-e, Chemetron Corporation. "On significant new use, how is it defined? If a chemical is already on the inventory list, is the manufacturer supposed to check if his use is a significant new use. In recordkeeping will the manufacturer have to list all ingredients of his mixture including chemical formula? How will confidentiality be maintained?"

Three questions in that.

MR. JOHNSON: I will reply to them simultaneously, how's that.

Significant new use has not been specifically defined yet, but we will be defining that as we go forward and prepare the rules for premanufacturing notification. It will have to do by and large with whether there is going to be a significant change in the population at risk. And, it is going to be difficult

to define generally and uniformly.

But, I will give you an example of the kind of thing which would be involved. If there was a chemical which was used for industrial purposes only, within a specific industry, and all of a sudden that same chemical would be used for, let's say, household use and distributed widely around the country, that, of course, would be a significant new use; if you increase production of a chemical say from a thousand pounds a year to say a million pounds a year, and distribute it across a wide section of the country, that would be considered a significant new use too. But, we will be going through rule development on that and be very carefully defining that that summer.

MR. DUPREY: The question on the environment?

MR. ANDERSON: I have three questions to answer here.

If a chemical is already on the inventory list, the manufacturer is supposed to check significant use of a chemical. Actually

if the chemical is on the inventory list once, the uses of the chemical will not be on the inventory list at all. It is really subject to a rule that that we're going to be developing that the responsibility is on the manufacturer, really, to determine in advance of a significant new use. He can ask us and we will tell him, of course. But the use won't be on the inventories themselves.

The second question is in record-keeping will the manufacturer have to list all the ingredients of his mixture including chemical formulas, how will confidentiality be maintained; we will have a specific system for petitions by the manufacturer to keep this information confidential, and we will have specific systems set up to keep it confidential. We are going to do our level best in doing that.

But, again, I want to say if there are health and safety studies involved in a chemical substance, we cannot and will not keep that confidential.

MR. DUPREY: Okay.

On another question on the

inventory list from Larry Holladay, H-o-l-l-a-d-a-y, Great Lakes Chemical, West Lafayette, Indiana. "What do you advise a company to be doing to make an inventory list? What should be on it besides the chemical name; such as, how much made, where did it go?"

MR. JOHNSON: The inventory list, again, will just be a list of chemical substances. The manufacturer should obtain a copy of the published list from the Environmental Protection Agency. As I said that within the next thirty days or so will be published.

We had intended to publish that in the Federal Register, but we were advised by the people at the Federal Register that it was going to cost the government I think it was two hundred ninety four thousand dollars to publish the list, the cost to the government. What we will do instead is to have it published -- or printed, ourselves, and we will distribute it as widely as possible. We will make thousands of copies available to the Regional Office, we will be dealing with trade associations, we'll have our industry assistant's office be responsi-

ble for distributing the list as widely as possible.

It is also very possible also that we will have the listing available in computer form for access by individual companies that want to check their manufacture against that list, although that has not been made final yet.

If you are a manufacturer or a processor and you would like to have computer accessibility let us know over the next thirty days or so that you would like to have that accessible and we will see to it that we do it.

We are going to exert every effort and do what we can to make the chemical list known as widely as possible so that the manufacturers, especially small manufacturers will have a opportunity to see the chemical list and checked whether or not their chemical substances are on the list.

The inventory itself, when we ask for information from manufacturers on the inventory, all we're asking for in the initial inventory is confirmation first that they're

making the chemical substance, and there are forms specifically for that, and the name and the address of the manufacturer, and the responsible party involved. Or, if it is a substance which is not on the list and they want to have it put on the list, there is a second form for that.

We are asking for only that information, confirmation of chemical substance manufactured, or new chemical substance manufactured, and the name and address of the manufacturer and the responsible party. We want to make this process as simple as possible.

There will be other reporting requirements and records later on developed under section eight A of the law, but not on the initial inventory.

As I said earlier, some people feel we should ask for more information on initial inventory and production and the like, but we're not going to do it now. We want to make this as smooth a process as possible. Because, one of the tests of the agency is going to be next fall, November or December, on

the publication of the initial inventory, on our response to premanufacturing notification, how well you do in processing those, protecting the people, and also doing it in an expeditious fashion. We want to have the machinery as smooth as possible.

MR. DUPREY: Here is a question also on inventory from E. Rooney, R-o-o-n-e-y, Apco Oil Corporation. "What is the date before which a manufacturer of chemicals must register an old chemical?"

MR. JOHNSON: The final list -- the initial inventory list will be published on November the 11th, 1977.

We are going to print up and distribute the candidate list of the 33,000 chemical substances within approximately the next thirty days and distribute them as soon as possible.

MR. DUPREY: I have two questions here that are really on the same train that you will have to answer I am sure.

They're from Jack Pulley, P-u-l-l-e-y, from Dow Corning and M. Catherine

Ingram, I-n-g-r-a-m, from Goodrich Chemical Division. "Can you be more specific on what constitutes a reasonable risk or unreasonable risk? Do you plan to define the six or seven levels of risk used in the Act, substantial risk, imminent hazard, risk, significant risk, significant adverse effects, unreasonable risk?"

MR. JOHNSON: I doubt very seriously that we're going to do that because you really can't do it on a general basis.

We are going to by -- by example by the rules we developed on record-keeping and the process we following in reviewing premanufacturing notifications and regulations we develop on specific chemical substances limiting manufacture to that, to establish a record as we go into the future, ask what unreasonable risk means. It has to take into account, of course, the impact on human beings, the number of human beings involved, the level of toxicity. It has to do with people employed, population as well, it has to do with the impact upon other forms of life, all other forms of life.

It has to do with the cost of controlling the chemical substance or substituting for it. That is why I think the Act is quite properly calling for the chemical specific rule in which you address the question a chemical at a time.

We were doing it for polychlorinated biphenyls, we were doing it for fluorocarbons because you cannot establish a general statement of unreasonable risk.

With regard to other terms such as substantial risk as in section eight E, we're going to try to get out guidance over the next month which defines the information that we want to have at hand and the form it should take, and who should supply it to us. But, it might not be entirely satisfactory to the people who are going to be responsible for sending us information showing substantial risk.

We really -- I think it is a case of expecting people to use their best judgment to make a good faith effort. If it is common sense to them to consider substantial

risk is involved to people or other forms of life we want the information sent to us. And too, if you're going to err, err on the side of being conservative in trying to protect human beings and other forms of life. Because, as I said earlier, the policy in the Act which talks about developing information and responsibility being upon the manufacturer and processor, you really should work out so that you consider as part of your normal dealings in manufacturing and distribution and commerce, the impact upon the environment and human beings that are associated with the chemical substance. If you make a good faith effort it will be recognized as being a good faith effort. We can't ask you for something you out of ignorance cannot deliver.

MR. DUPREY: I have two questions from Sherman Smith from Fluor Pioneer. I think I can answer the first one, "Will the Water Pollution Control Act or the Clean Air Act be amended to show or reflect the findings related to the Toxic Substances Control Act studies and when could we expect to see these

amended regulations dealing with emission or effluent limitations."

I think at least the first part of the answer would be that the Act specifically requires us to use the Clean Air Act or the Water Pollution Control Act first, and then only if we find that those Acts are not adequate in our judgment to protect the public interest, do we use the Toxic Substance Control Act.

I think a good example is in the slide show which we are having on this evening on asbestos. Where some asbestos studies on that subject comes out that some of the asbestos standards need to be amended in the Clean Air Act, and I am certain that that would be the direction the agency would go in.

MR. JOHNSON: That is true. Also, Bob, we are to look at other Acts like the Food, Drug and Cosmetics Act, or the Occupational Safety and Health Act before we look to the Toxic Substances Control Act.

If there is an Act other than

one that the Environmental Protection Agency administers, which we believe would be a more effective instrument for regulating a toxic chemical substance, then we're to make a request to the agency responsible for that.

They don't have to legally follow our request, but I would expect that another agency would have a difficult time not taking any action when we make a request.

MR. DUPREY: The second part of this question is, "If after a manufacturer submits a notice to EPA saying that the chemical under question is safe, it is found to be unsafe, is the chemical company criminally liable for furnishing false information. If they are not, I suggest that a responsibility clause be added, making the submitting company responsible for submitted statement."

MR. JOHNSON: I am not an attorney, so I will go ahead and answer the question as best I can.

If information is sent to us in good faith in premanufacturing notification, and the manufacturer determines that his chemical

substance really will not constitute an unreasonable risk, and if we, the Environmental Protection Agency, review that, and agree with the manufacturer, then we could hardly hold the manufacturer liable.

If information is developed subsequent to that which shows that there is harm to human beings or the environment, then, I think, at that time, we would propose either a testing rule or a rule limiting the manufacture or distribution or use or disposal, and that goes through the fluorocarbon product that we're doing now with polychlorinated biphenyls.

I would expect that is going to happen. As I said earlier, we are not obviously a perfect agency, and the extent of information not only in our agency but around the world on toxic chemicals is very small. And it is very likely chemicals will pass through the premanufacturing screen in the future be shown to cause harm. We want to keep that number as small as possible but that is going to happen.

MR. DUPREY: Another question on the inventory, from Norbert Schlessor, S-c-h-l-e-s-s-e-r, that is probably pronounced wrong. "Will the inventory list include gasoline, motor oils, distillants and other petroleum products? If so, will gasoline be listed in total or as each of its possible two dozen components?"

MR. JOHNSON: I was asked that question in New York last week and I didn't have a good answer then.

In the initial inventory, I mentioned that we were going to list chemical substances in alphabetical order by their names, and by chemical abstract system, and by chemical number, their chemical formula, alphabetically. Also there is going to be a list of chemicals which you can't identify that easily.

It is possible that things like gasoline might be included in that last part, because as it was pointed out by a man from one of the petroleum companies, there are a lot of hydrocarbons in gasoline. And it is

a very difficult task to list all the hydrocarbons present in gasoline.

From his point of view I can sympathize with the work you have to do.

From our point of view, however, looking at the point of view of the agency, suppose we would like to define the impact of some hydrocarbon fraction of that gasoline upon the population at risk. And suppose we wanted to conduct an epidemiological study, or found it necessary because we have some information showing that there was a health impact, or impact on other forms of life. Looking ahead to the future, I think that the agency would like to have the hydrocarbon in the gasoline defined, and to conduct the epidemiological study that way rather than to do the epidemiological study with a catch all like gasoline itself.

But, here is a case, it is not going to be the last case, where we have a conflict really in our basic goals. And it is going to be something that is going to have to be refined as we go ahead into the

future to make our relationships more smooth.

MR. DUPREY: This is a different type of question from Roy Porteous, P-o-r-t-e-o-u-s, Winnetka Environmental Council. "Has Mr. Lance rejected EPA's request for the funds necessary to implement the new Act?"

MR. JOHNSON: In the last information we have from the office of management and budget for the whole agency, the agency is to get six hundred additional positions beyond what it began with fiscal year '77 with. Of those six hundred positions, two hundred and eighty will come for the implementation of the Toxic Substances Control Act. That is for both fiscal years 1977 and 1978. That is not different in total numbers for the two years than was given to us under the Ford administration. But, what is different, is we're going to be allowed to go ahead and hire all the people under the FI positions right now.

That is a small number to begin with. It is now my belief and other people's belief that to carry out this Act effectively,

especially to go on into the future, there will undoubtedly be a great growth in the number of people in the agency administering the law. It is going to be a very tight squeeze at the beginning.

And we look forward, for example, December 10th next year -- or this year yet -- getting -- getting premanufacture notifications to us, and we have to process them within ninety days. We are going to get an expected one thousand each year, that is three every day. It is really going to be difficult for us to do an adequate job on that.

I was present yesterday when the acting administrator, John Corals, testified before the House Appropriations Committee, and he made the statement that he thought eventually implementation of the Toxic Substances Control Act would require a staff of literally thousands to review chemical substances to determine their impact upon the environment. Because we are talking about some thirty thousand chemical substances which are in commerce right now, a thousand new ones each year. Information

from groups such as the World Health Organization that are looking towards formations of cancer who are saying that only fifty percent of the cancer in the world can be specifically tied to non-environmental causes.

I think it is without a doubt, as our information becomes better, it is going to cause us to ask new questions and go further and examine what is making an impact upon us, in the air we breath, in the water we drink, and the food we eat.

And without a doubt, I think that there is going to be expansion of the Environmental Protection Agency to carry out this law. A lot of people are going to look at that and say we have got another army of bureaucrats that are going to regulate us. But as I said earlier, that is the burden upon the agency to do and in a way which protects human beings and other forms of life and does not unduly complicate commerce.

It is not going to be entirely possible to do that smoothly, but that is going to be our goal.

MR. DUPREY: The next question is from Lee Dietrich, Abbott Laboratories, D-i-e-t-r-i-c-h. "Are waste solvents sold for recovery covered under this Act? If these solvents are covered, must the exact composition of these mixtures must be known? For example, if the mixture is ninety to ninety five percent of a known solvent, but the remaining parts are unknown percentages, must these percentages also be identified before being sold?"

MR. JOHNSON: That obviously is going to be a difficult area.

If the person doing the recovery, really, from waste solvents is really processing the chemical, as you would think he was, then the law does cover it.

It is going to be extremely difficult, obviously, to identify the component parts and waste material. I don't know right now in all honesty how we would approach the definition of materials in the waste solvents that are going to be processed. I really don't know an answer for that right now.

MR. DUPREY: The next question is from

Biemeck, B-i-e-m-e-c-k. "Thus far, the brunt of the discussion has been focused on chemical manufacturers. Please describe the impact on industrial users of chemicals, regarding such things as recordkeeping, monitoring, et cetera? Where will the major emphasis of the Toxic Substance Control Act be placed, on the chemical manufacturer or the industrial user?"

MR. JOHNSON: The law discusses the application of the various sections of the Act to chemical manufacturers and processors.

The area which is a gray area right now, is it is hard to differentiate between a processor and a user.

We are going to, as we begin the Act and apply general recordkeeping, talk about processors in terms of basically those people that take chemicals do something to them, and distribute them to commerce again.

At the same time, however, we have to recognize that we have to have a relatively broad definition for processor, because if an industrial company uses great

quantities of a chemical substance, and there is a significant population at risk, both employee population and people outside, we have to have really some flexibility in addressing those issues.

I will give you a specific case. I would myself, and I am just speaking for myself right now, because this is still under discussion with our office of general council; if there was an assembly plant that purchased large quantities of say, trichlorethylene as a degreasing solution, and degrease steel parts, I would consider myself as a logical user. It would not be basically covered under the law. However, if we look ahead into the future and it is determined that trichlorethylene is really information we don't know now, is quite toxic, then I think it is the opinion of our General Counsel that we might want to ask for recordkeeping there and try to have a broader definition. As we being, we would want to do that.

If we apply such a definition as we go on into the future it would be on a

very chemical specific basis. Again, in the same sense that we didn't want to leave any gaps between this Act and the Federal Insecticide, Fungicide, and Rodenticide Act. We wouldn't want to leave any gaps where there are significant populations at risk that aren't covered.

It is our intent now not to consider that as a process that we have in the general recordkeeping and the general inventory.

But, we are trying to be as flexible as we can. We don't want you -- we don't want to build a definition now which is going to mean that at some time in the future some large segment of the population, human beings and other forms of life is left unprotected.

MR. DUPREY: This question is from Victor Denslow, Amoco Chemical Corporation, D-e-m-s-l-o-w. "If a new substance is later added to the inventory list, does it then become an existing substance, such that subsequent manufacturers of the same substance do not have to

make a notification of a new substance?"

MR. JOHNSON: Yes, that is correct.

As soon as -- after premanufacture notification, if we agree that it should go into commerce, then it is added to the existing chemical list.

MR. DUPREY: Mr. G. Cooper, DeSoto Incorporated. "In the premarket notification process, the manufacturer faces the burden of demonstrating a new substance will not cause unreasonable risk to health or the environment. Does the agency believe at this time that this can be accomplished without conducting toxicity testing?"

MR. JOHNSON: I don't think so. It depends upon the chemical substance and the classification.

As we go forward this summer and define the information we want to have sent into us in premanufacturing notification, we will define as best we can the test that will have to be conducted, or the information that will have to be sent to us.

I really couldn't envision now accepting information which doesn't include

toxilogical information.

I will say if information exists for that chemical substance in the literature and prior research, that can suffice. It isn't necessary, for example, that a manufacturer conduct new testing on a chemical substance. But, it probably -- if we're talking about new chemical substances that may be necessary.

MR. DUPREY: The next question is from Neale Byrnes, Liquid Carbonic, Chicago, B-y-r-n-e-s. "What constitutes a non-essential use of aerosols, such as, would a sterilizing gas using a freon-12 propellant be considered essential?" Relating to the fluorocarbon.

MR. JOHNSON: We have right here in this room the man who led the development group for the Environmental Protection Agency for furic carbon regulations, and he's sitting right down here. I will ask George Worth to come down here and answer that question.

MR. WORTH: Basically what the agency is considering now for a definition of aerosol propellants, would exclude the freon-12 --

the exclusive use of freon-12 in cans as a freezing agent.

Basically the agency is defining an aerosol propellant as that use of a fluoro-carbon mixture to propel some other substance from a can. That means if the fluoro-carbon is used as the active ingredient it would not be banned.

MR. DUPREY: This next question I think is a quite good one, from M. P. Shinkle, S-h-i-n-k-l-e, from EMS, Inc. "EPA has admitted to difficulty in administering pesticide affairs and regulations. How do you expect to circumvent such problems with toxic substances?"

MR. JOHNSON: Well, I can't guarantee it, obviously.

As we go forward though -- we're starting from the beginning through meetings like this, with a -- the people that we're trying to protect and the people who are going to be regulated, and we're trying our level best to make the system as smooth as possible. We are not going to go out on fishing expeditions for information that is

not going to be used. We are going to be quite specific in what we determine to do. We are going to be quite specific in the information sent to us on premanufacturing notification and the series of tests involved.

I hope we have learned from the mistakes of the pesticide program. We have conducted a zero base budget for the office of pesticide, the change should be made there. At the office of toxic substances we hope to gain from that.

I would expect that the office of pesticide programs would learn from their mistakes also.

In our office right now there are organizational changes and procedural changes within the agency to overcome those past mistakes.

But, you can't, of course, except on the promises from me on this, you have to judge us on our performance.

I think not only in the development of our strategy going ahead into the future having meetings like this, but I think period-

ically we will come back to groups like this say a year from now, then you can judge on the basis of our performance, you can pass that same question on again and determine how we have done.

MR. DUPREY: The next question is from M.J. Arnold, A-r-n-o-l-d. "What are the responsibilities of a shipping company when a manufacturer provides them with a chemical for export?"

MR. JOHNSON: Could you repeat that?

MR. DUPREY: Responsibilities of a shipping company when a manufacturer gives them a chemical to export to a foreign country?

MR. JOHNSON: Under specific section of the Act, the agency itself, really, is to notify the country that is going to receive the material, what it is getting, if there are specific rules for testing and regulations on hand in this country that those rules are to be transmitted to the receiving country. If there are health and safety studies associated with the chemical, we are to transmit those, or make lists of those available to the receiv-

ing countries.

It is up to us, really, to get information on the material which are to be exported. And it is obvious that in defining that under the section of the Act applying to exports that by rule we're going to have to establish procedures for which we do have them.

MR. DUPREY: Well, Ken, is it conceivable if the labels required on chemicals, that that -- that there may be something in terms of a rule or the labeling included in the shipping?

MR. JOHNSON: I don't think that we want to hoist upon any country a product that we don't -- we label here. But, I wouldn't think that we would ask them to remove the label, I would think they would just leave it on.

MR. DUPREY: I am thinking in terms of the shipper in terms of making sure that that is kept packed.

MR. JOHNSON: Yes, it is possible.

MR. DUPREY: A question from Dr. Salem,

S-a-l-e-m, S-h-a-i-r, Dearborn Chemical Company. "Please discuss the candidate list and the final list, the list which will be published on November 11th, '77, and how soon after the publication of the final list, the inventory list must be submitted to EPA."

MR. JOHNSON: The inventory list is a list of chemical substances now in commerce or which have been in commerce within the last few years. The agency will publish that list on November 11th, 1977.

The purpose of the list is to establish a starting point after which -- thirty days after which any chemical substance which is not on the list must be submitted by the proposed manufacturer to EPA in advance of the manufacture. So, it is really to establish sort of an initial starting point and not to interfere with chemicals now in commerce.

We are going to publish a list which we believe constitutes chemicals in commerce in the next thirty days or so, print it up and send it out. On that list will be

approximately 33,000 chemical substances with up to five names, published in alphabetical order according to the chemical name, published in order chemical aspect service number, published by chemical formulation, and alphabetical order, so that the manufacturer can examine the list and determine whether his chemical substance is on the list. If it is, he fills out a form which confirms it; if it is not on the list, he fills out another form which is used to add a chemical substance to the list.

Next November 11th we will publish the final list in the Register. Thirty days after that on the 10th of December if a chemical substance is to be manufactured and is not on the list, they are to come to us for premanufacture notification, our review over a ninety day period to determine whether it is allowed to be manufactured, whether additional testing is needed, or whether it should not enter manufacturing without some limitations upon it.

I was asked the other day at a meeting like this if there was going to be any

provision for sort of late filing after November 11th. It is possible that if there is sufficient justification given to us we would extend it after November 11th. But, it would really have to be demonstrated to us beyond a shadow of a doubt that a chemical substance just couldn't get on the list before November 11th.

I would think as a general rule we would not accept new chemical substances after that. But, I am not going to close the door entirely.

I would think November 11th is the date you should get your materials on that list if you have any reason to want to go ahead and continue manufacturing without premarket notification.

MR. DUPREY: The next question deals with confidentiality, from Mr. Thompson, T-h-o-m-p-s-o-n from Keil Chemical. "What will be done to prevent premature public disclosure of early finance of possible adverse effects of a chemical class, that on further testing may be found to be erroneous, so that the producer will not be hurt in the marketplace or by

public image?"

MR. JOHNSON: Again, I can't give you the perfect answer to that.

Health and safety study information, of course, would be made available to the public. And I don't know how we would know in advance that the information may be erroneous.

And there undoubtedly is going to be cases where there is going to be adverse impact upon the manufacturer or processor on the commercial distribution of the product.

That is going to happen in another area that I can define for you right now. I mentioned earlier that we're going to have -- we do have an interagency testing committee that is going to specify up to fifty chemical substances for testing. And as I said before, it will probably be classifications rather than individual substances. These are test required because a chemical substance is suspect of causing harm to human beings or other forms of life.

The very listing of the chemical substance for testing is going to be used by

a great segment of the population as being reason for not using that chemical. There is no doubt about this, there is going to be an adverse impact upon the manufacturer of that chemical.

It is also going to be recognized by the public that the interagency committee and the Environmental Protection Agency placed on a priority list chemicals for testing that that undoubtedly is going to be the initial list from which future regulatory actions are going to be. Again, it is going to have an impact upon the manufacturer and the processor, and there is no doubt about it. I don't know how you can get around that, that is just the facts of life.

MR. DUPREY: I have a question from Ira MacDonald, M-a-c-d-o-n-a-l-d. "What provisions of the Act would preclude another PCB incident wherein a coop feed mill inadvertently mixed a fire retardant chemical in animal feed?"

MR. JOHNSON: That is a question which came up yesterday at the House Appropriations Committee hearing on Environmental Protection

Agency budget for FY 78.

The congressman from the state of Michigan raised that question, how could this Act prevent such an occurrence. And the response is that we're not going to be able to prevent human error in every case.

It might be possible under this Act, if we have reason to believe for a chemical substance like polychlorinated biphenyls that is highly toxic, information is obtained by the agency to show that, and we do know that it is being manufactured in such a fashion that there may be contamination, as in this case in cattle feed, it may be possible under the Act to identify really how the materials should be manufactured and to have more or less a system which would keep it as far as possible from any possibility that human error would introduce it into cattle feed.

That is not going to be a perfect system. It is not going to be perfect because as I said to begin, we won't have information on all these toxic properties of all the chemicals.

It is going to be some time before we will be able to identify differences in manufacturers.

I hope sometime in the future that we are able to act in advance in all chemicals. That is going to be our goal. I am not sure that we will be able to do it in every case right away, but we are going to try our level best.

MR. DUPREY: This question is from Bernard Korn, K-o-r-n, American Hospital Association. "What hospital involvement do you envision in the implementation of this Act?"

MR. JOHNSON: If I understand the question correctly, if we're talking about what medical help we are going to look for, we are going to try as much as possible to make use of professional judgement and expertise in our policy advisory committee, in our interagency advisory committee with representation from those offices within the Department of Health, Education and Welfare that have medical experience.

We have been working with the Center for Disease Control, for example, National Cancer

Institute, National Institute of Occupational Safety and Health.

If representatives from the American Public Health Association want to send us -- or Hospital Association wants to send us nominations for policy advisory committee, they would be given very serious consideration.

MR. DUPREY: I have a couple of questions on the same item here and I will just read one.

Alvin Hass, H-a-s-s, Chemplex Company. "Will you have specific rules as to exactly what type of employee records information is to be kept for thirty years?"

MR. JOHNSON: Yes. That rule development group is just -- just completing its development plans now. It is being sent to the acting administrator now for his approval. And we will define within that rule in the future what we expect to be kept.

MR. DUPREY: Okay. I want to leave some time for people to make some statements. So, I am cutting down some of the duplicate questions here.

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question from James Haney, H-a-n-e-y, from Neenah, Wisconsin. "You indicated that EPA has had preimplementation consultations with some nineteen organizations or interested groups. Could you identify the groups with whom you have met in order that we might evaluate the diversity of opinions that you have received to date?"

MR. JOHNSON: Well, I can't name them all.

In the group I can name several chemical manufacturing organizations like manufacturing organizations for example, we have had some soap and detergent manufacturers organization involved, we have had representation from the Oil, Gas and Atomic Workers, Oil, Gas, Chemicals and Atomic Workers Union. We have had representation from I think the Sierra Club and the Environmental Defense Fund. It is a wide ranging representation of people.

If the person that asked that question will leave a name and address I will see to it that the identification of each and every group and representative on that committee of nineteen be sent to that person.

MR. DUPREY: Most of the additional questions I have, although they are different requests on some of these items are along the same line. I think rather than proceeding on these people who would like to get up and make more -- make a remark rather than ask a question, I'd prefer to do that now. We can return to the questions later if there aren't many people that want to do that. Or some of these questions, I think can come up in the panel sections that we have, specifically the testing ones, which most of the rest of the questions are names and inventory or prenotification questions.

So, if people want to approach the microphone and make some remarks, I would prefer that you limit them to no more than five minutes and to identify yourself and spell your last name for the reporter. If there are people that want to do that, use that approach.

I do have a lot more questions if you'd rather I continue on with the questions.

Is there anyone in the room that would like to make a statement?

Okay. I think we should just continue with the questions then. I am learning a lot from this too.

This question here is from E.R. Bly, B-1-y. "Will the rules specify the codes of manufacture and general specifications to be used. For example, a material may be stored in coded vessels, all sorts of drums or even paper sacks. The possibility of contamination varies greatly with the choice. How will this be controlled? The same applies to contaminant facilities?"

A very specific question.

MR. JOHNSON: If there is reason to regulate the manufacture or distribution or use or disposal of the material it will be done on a chemical specific rule development basis. And the determination will be made as to the most effective point to apply the regulation.

It is possible under section six of the Act to limit how material is manufactured. And there may be specific limitations as to the containers which can be used or may be specific limitations which says that the

process has to be totally enclosed.

As a matter of fact the Congress itself on PCBs provision of section sixty of the Act stated that as of January 1st, 1978, PCBs can only be manufactured in a totally closed manner.

But those specific provisions will be determined during the rule making process by participation from everyone concerned, adequate time to identify the specifics of the situation, and we're going to do our level best not to pass rules which are just generally sweeping rules which won't recognize the manufacturing, processing, and placing in an undue burden. We are going to call into consideration with us the people who are going to be regulating as well as the people we're trying to protect. Everybody has a fair chance to make a statement.

It is going to be enormously complexed, obviously. And I just hope we can do the best job possible.

MR. DUPREY: A question from Bruce Bornhorst, B-o-r-n-h-o-r-s-t, Insurance Company of North America. "Have priorities been established for

investigation of chemicals as to mode of action, mutagenic, synergistic, et cetera?"

MR. JOHNSON: That is really one of the responsibilities of the testing committee, is to establish a list of chemical substances for which new tests will be required. And during that obviously they are going to have to consider the types of tests that are to be applied.

We within the Environmental Protection Agency, and other agencies involved, are discussing whether we can establish common or at least compatible testing sequences in which we try to screen out as much as possible chemical substances for which we would have no further interest and which would be essentially cleared by an early test, from those which we would want to investigate more deeply. And then tear by tear, we would go down the list of tests really to further define information upon which those are harmful. We are going to do that very systematically not only within our own agency but with other agencies which are involved, especially those from the Department of Health, Education and Welfare and from the Occupational

Safety Health Administration.

MR. DUPREY: I have some other questions about the small business exemptions. Bob Lippe, L-i-p-p-e, Arnold Engineering Company. "Is there any indication how small companies who are industrial users will be exempted from the act requirement, for example, by total size, sales, et cetera, or by volume used of certain chemicals on the candidate list?"

And also he asks, "How does this Act relate to the Illinois Toxic Substances Act?"

MR. JOHNSON: We are, during this summer going to be defining what we mean by small business. And, I am not sure how the definition is going to come out.

We will be working with the Small Business Administration. And I want to repeat that anybody here who has a good idea as to how we should define small business, please send in your definition to us.

The idea of this kind is to accept small business from sections eight A recordkeepings provision of the Act, not to

put an undue paper burden upon them. As this has been true quite frankly with other pieces of legislation applying to the environment, we wanted to keep as much as possible the red tape and paperwork away from small businesses.

But, at the same time the sections of the Act which pertain to health and safety studies, the sections of the Act which pertains to regulation of chemical substances do not exempt small business, just the general recordkeeping regulations in section eight A.

I think the slide shows by the end of this summer we hope to have a definition of small businesses, and we solicit your interpretation.

MR. DUPREY: There was a second part of that question about relation to the state law.

MR. JOHNSON: I think actually Bob --

MR. DUPREY: Well, basically the Act -- I am not nearly as familiar myself with the provisions of this particular state law, but the Toxic Substances Act does provide that states can regulate toxic substances. The problem is in the area of testing. When we put out

our testing requirements the state is prohibited from issuing one on that particular chemical, because obviously we get into a lot of complications.

However, the state does have the right to regulate toxic chemicals and in fact regulate it more stringently than we do if they obtain an exemption on that particular section -- section eighteen.

MR. JOHNSON: Section eighteen applies to free exemptions.

MR. DUPREY: Here is a question from G. Goodman, G-o-o-d-m-a-n. "What procedures and timetables are being followed for implementation of section ten providing for research, development, collection, dissemination, and utilization of data in consultation and cooperation with the secretary of HEW and heads of other departments and agencies?"

MR. JOHNSON: With our regard to involvement with HEW, we have met with a group headed by the assistant secretary for health on January 14th, to discuss establishment and an agreement between HEW and EPA on sharing data and

working towards a common purpose.

From the HEW side as well as the assistant secretary for health, we have Dr. Frederickson of the National Institute of Health, we have representation from the Center for Disease Control, the National Institute of Environmental Health Sciences, and all of the specific groups within HEW, with whom we'd like to work. And we anticipate that we will develop a basic agreement between the two agencies which will bring together our information, development and utilization practices.

We have already established with the National Library of Medicine computer programs for toxic substances. We have formed within the office of toxic substances a task force to look at information, development, and utilization of which I consider to be the life blood of the whole implementation process for the Toxic Substances Control Act.

And I would say over the next several months, we would have some concrete results applicable to section ten from them.

With regard to research and development, I think that one of the difficulties with the agency right now is that we have not had adequate research and development on toxic substances. We really have not as an agency had the direction we should have had in research and development. We haven't had the resources to carry out the program. I think it is going to be essential in looking forward into the future to further develop the information upon which our success is going to -- in implementing the Act is going to be necessary. It is going to be necessary to get better and better funded research and development, there is no doubt about that.

MR. DUPREY: The next question is from E.H. Hurst, H-u-r-s-t from Nalco Chemical. "Will small quantities of chemicals sold as testing reagents be excluded in inventory lists and or under section five exemption sections?"

MR. JOHNSON: The law excludes small quantity of chemical used for research purposes in the rules to be proposed on the initial

inventory. We talked about that. We don't define the quantities which we consider small, we just state that it had to be used for research purposes, supervised by somebody that was qualified in research, and establish a general definition.

There were some people that said we should say five hundred pounds a year production is considered small, but we decided not to do it that way, but to define it in terms of chemical needed for research purposes and to be used only for research purposes to be exempt.

MR. DUPREY: This question is from Roger Keller, K-e-l-l-e-r, Mallinckrodt, Incorporated. "If a new chemical is subject to a testing rule, will the testing rule expire as soon as the new chemical is placed on the inventory list? If not, how long will the testing rule remain in effect after the chemical has been listed on the inventory?"

MR. JOHNSON: If we require testing of a chemical substance which is a new chemical substance, and ask that the test be completed,

that essentially holds up the manufacture of the chemical substance until the testing is completed to our satisfaction.

In the testing rule we would define the test procedure to be carried out and the time period in which it is to be carried out.

The manufacturer has the right to object to any testing rule like that which holds up the administrator's decision, and then it goes to the courts, essentially, to decide the issue.

But we have to under the testing rule, in section four, we have to define the time period required for the test, it goes through the rule making process with public participation involved.

MR. DUPRE: A question from Gregory Skomp, S-k-o-m-p, Indiana State Board of Health. "Will the new PCB regulations specify water quality standards? Does the federal government intend to approve the use of Mirex in the way against the fire ants in the South?"

MR. JOHNSON: I will let George Worth

address the question on PCB since he's involved with that development group.

MR. WORTH: The question was; will the PCB regulations include water quality standards, no. The water quality standards already has been established in 307A, effluent -- toxic effluent guide lines, 30 section A of the Water Pollution Control Act. This regulation will only cover disposal requirements, labeling requirements, and then the definition surrounding the manufacturing.

MR. JOHNSON: In answer to the last part of the question I am not sure myself under the Federal Insecticide, Fungicide and Rodenticide Act what the specific Mirex regulation is. Maybe George knows.

MR. ALEXANDER: Actually, Mirex has a -- I don't know how to explain the registration, but it has a special registration for use in Mississippi and that area that was granted last year by EPA. It is a very limited use.

MR. DUPREY: I have a series of questions from John Goulias, G-o-u-l-i-a-s, Shell Engineering Associates. "One: will emergency res-

ponse planning be implemented as part of the policy section two B two? Two: if so, how will the office of enforcement document be related to the Toxic Substances Control Act? Three: how will confidentiality of formulas of mixtures of toxic substances in manufactured products be handled? Four: how will toxicologists from EPA, universities, industries, et cetera, be organized to review and document chemicals on the EPA list?"

Some of that might have been answered.

I might say with respect to the enforcement document that is one that we're using in the regional offices, and the documents was issued to us as a document to take care of present emergency problems that come up with toxic substances, so that existing authorities that we have under the Clean Air Act, Water Pollution Control Act, and the Pesticide Statute can be used to deal with those problems.

As the Toxic Substances Control Act develops further, it is my understanding

that the emergency response document will be amended to include provisions in the Toxic Substances Control Act.

MR. JOHNSON: On the confidentiality, if a manufacturer or processor wants to keep this information confidential, say in the initial inventory or under a testing rule later on, or one of the enforcement rules, they simply petition the agency and make a case for confidentiality and then we will keep the information confidential.

Except, I will repeat again, we cannot keep health and safety study information confidential according to the specific requirements of the Act.

On how we are going to organize the toxicologists, I will begin by saying that the interagency testing committee itself, in determining the list of chemicals which are to be placed in priority for testing, will include toxicological expertise from all the agencies involved. And toxilological considerations are going to be at the head of list of criteria that are going to be used in defining that list

of chemicals.

The agency itself will hire, of course, toxicologists to work under the direction of the assistant administrator for toxic substances. It's entirely possible that if, as the agency moves ahead into the summer, it may combine organizationally under the assistant administrator for toxic substances both the implementations of the Toxic Substances Control Act and the implementation of the Federal Insecticide, Fungicide, and Rodenticide Act. And it is possible that the new administrator may decide to bring together in a common pool, in a hazard assessment, or hazard evaluation toxicologist from both programs, but I can't really determine that.

MR. DUPREY: I have one last question here from James Leenhouts, Dow Chemical Company, L-e-e-n-h-o-u-t-s. "I am concerned about the apparent attitude difference expressed in "what will the next one do to you - find out at EPA's information meeting" and "the main purpose of this meeting is to solicit comments on imple-

mentation."

This question refers to our brochure. We kind of -- it does seem a little schizophrenic. Partly, we were interested in certainly giving out the information we knew about where we were and what we were doing, and we were interested in getting input from the public as well at the same time. It sort of had a dual purpose.

And hopefully especially during the afternoon sessions, we will be getting quite a bit of that input, we have members from industries, people from environmental groups, and state agencies on these panels to discuss some of the questions that need to be discussed. And, of course, I think most of the input is going to be a continuing thing to the development of these regulations. I hope that people will take the time to evaluate them carefully and submit their comments on them as we go forward so we do get this implemented.

There is a second part to this question and that is, "Also, how does EPA

intend to relate polyvinyl chloride with PCBs and PBBs?"

MR. JOHNSON: We are going to treat each chemical in our testing and rules making as a separate entity basically.

We do have, of course, rules under the Clean Air Act for vinyl chloride. It is possible going into the future to do more than we have done under the Toxic Substances Control Act. But, we treat them as specifically different chemical combinations as will PBBs.

It is entirely possible as we go ahead into the next few months that we are going to add to the chemical substances that we have rule making on going on PCB and fluorocarbons, we might add to that additional chemicals, and one of those under serious considerations of course is PCBs.

MR. DUPREY: Okay. Thank you. That completes our question and answer session. We will meet this afternoon.

(Whereupon, a recess was had until 1 P.M. this date).

STATE OF ILLINOIS)
) SS
COUNTY OF COOK)

SUSAN PANICO DIME, being first duly sworn,
says that she is a court reporter doing business
in the City of Chicago and that she reported in
shorthand the proceedings had at the hearing of
said cause, and that the foregoing is a true
and correct transcript of her shorthand notes,
so taken as aforesaid, and contains all the
proceedings of said hearing.

Susan Panico Dime

SUBSCRIBED AND SWORN TO
before me this 15th day
of March, A.D., 1977.

Ramona Hornick
Notary Public